Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, on or before June 20, 1995.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

A. Received on or before the deadline date; or

B. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1.A. or 1.B., above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 531. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Adrienne S. Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6630. Programmatic technical assistance may be obtained from Larry D. Edmonds or David Montanez, State Services, Birth Defects and Genetic Diseases Branch, Division of Birth Defects and Developmental Disabilities, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop F–45, Atlanta, GA 30341–3724, telephone (404) 488–7170.

Please refer to Announcement 531 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 14, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–9880 Filed 4–20–95; 8:45 am]

BILLING CODE 4163–18–P

[Announcement 523]

Innovations in Syphilis Prevention in the United States: Reconsidering the Epidemiology and Involving Communities

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for cooperative agreements to conduct research toward substantially reducing syphilis in the United States, especially in the southeastern United States, the region with the highest syphilis rates. Syphilis is linked to substantial mortality and morbidity through congenital syphilis, and through its ecologic relationship with and cofactor role in HIV transmission. Therefore, effective, innovative, community-based approaches to syphilis prevention may have an important multiplier effect on HIV prevention and adult and infant health in the communities where syphilis is most prevalent.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Sexually Transmitted Diseases. (To order a copy of ''Healthy People 2000,'' see the section ''Where to Obtain Additional Information.'')

Authority

These cooperative agreements are authorized under Section 318(b) of the Public Health Service Act (42 U.S.C. 247c(b)) as amended. Applicable program regulations are found in part 51 (b), subparts A and F of title 42, Code of Federal Regulations.

Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- or women-owned businesses are eligible to apply. Applicants must, however, document collaboration with each of the following entities:

1. At least one non-profit, public or private research institution (e.g., university, college, hospital, laboratory);

2. A public health agency in State or local government; and

3. At least one community-based organization (CBO) or other institution or agency with a track record for working with communities affected by syphilis in the project area. The CBO does not need to have a record of working on the problem of sexually transmitted diseases, only to have

worked with the communities that are affected.

To be eligible, the *project area* as defined under ''Program Requirements'' must have an incidence of primary and secondary (P&S) syphilis in calendar year (CY) 1993 above the PHS year 2000 objective of 10/100,000 and a total of more than 150 cases of P&S syphilis in CY 1993.

Availability of Funds

Approximately $1 million is available in FY 1995 for a 12-month budget period; the project period for Phase I (Preparation) is expected to be for two years. Four to five awards will be funded for Phase I. The awards are expected to range from $200,000 to $250,000, beginning in September 1995. Shortly before the completion of Phase I, recipients will compete for continuation of award in years 3 through 5 (Phase II—Implementation). Two to three awards are anticipated for expansion into Phase II research activities for the remaining three years of the project period. (Further details on Phases I and II is presented below under the heading ''Purpose and Outline of Program Plan.'') Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be based on satisfactory progress and the availability of funds.

Program Goals

By the end of Phase I (24 months), it is expected that:

1. Strong partnerships among research institutions, health departments, and at least one community-based organization will have been established or strengthened.

2. The epidemiology of the transmission of syphilis will have been analyzed to identify characteristics and target interventions to the most important mechanisms that sustain syphilis spread and persistence in the community (Component 1).

3. A programmatic intervention will have been pilot tested and assessed for its potential for measurably lowering syphilis transmission in a defined area while being acceptable to members of the affected communities and to participating organizations or agencies (Component 2).

4. A sensitive surveillance system for following trends in syphilis transmission in a population will have been implemented and at least one full year of baseline data collected.

5. A management information system will have been implemented to track activities and costs in syphilis prevention activities (Component 3).

At approximately month 18 of the project, applications for a competitive continuation award for the implementation and evaluation of a population-level intervention (Phase II) will be due. Fewer, larger, Phase II awards are foreseen for interventions that show the greatest potential impact and that are based on well-conducted research from Phase I. Supplementary guidance for Phase II awards will be provided to the recipients of Phase I awards.

Purpose and Outline of Program Plan

The purpose of this announcement is to generate new knowledge, tools, and strategies toward sharply reducing syphilis incidence, particularly in the southeastern States where incidence is disproportionately high. Congenital syphilis is closely linked to newly acquired syphilis infections in women, so an intensified focus on syphilis transmissions is expected to contribute directly to a principal, short-term PHS goal of eliminating congenital syphilis.

Phase I and Phase II of the research program. This research program is separated into two phases of activity and funding (Table 1). The fundamental goal is best understood in the context of Phase II (years 3 to 5 of the anticipated 5-year project), in which the grantees will implement and evaluate an innovative, science-based, cost-effective approach to reducing the transmission of syphilis in a project area.

TABLE 1

Phase	Project years	Grantees (No.)	Focus of activities
I	1 and 2	4–5	Preparation for innovative approaches to syphilis control and prevention.
II	3 to 5	2–3	Implementation of interventions and evaluation of impact on population.

However, CDC is not seeking final proposals for such Phase II intervention trials at this time because science-based, innovative approaches to syphilis prevention will require multifaceted preparation and planning. In particular, communities affected by syphilis should be represented more substantively than in the past in developing new approaches to syphilis prevention. This announcement, therefore, focuses on Phase I subject areas and solicits research proposals that will yield scientific findings and stimulate the building of multi-disciplinary research teams needed to guide and implement the Phase II intervention trial.

Areas of preparatory research in Phase I. During Phase I of this program, three key research components will be addressed:

1. Innovative uses of epidemiologic and behavioral science methods and findings about syphilis transmission in communities to direct prevention strategies.

2. Development of a programmatic intervention and pilot test of that proposed intervention before large-scale implementation; development of partnerships with communities affected by syphilis.

3. Development of a sensitive syphilis surveillance activity to be used in evaluating the efficacy and cost-effectiveness of efforts to prevent syphilis.

Further explanation of these Phase I activities can be found in the section ''Program Requirements.''

Program Requirements

This cooperative agreement is foreseen as an important element in a national reassessment of our approaches to syphilis control and prevention. To achieve the purpose of this program, the recipient will be responsible for activities under A. and CDC for activities under B., below:

A. Recipient Activities

1. Develop an overall framework to design an effective, innovative approach to syphilis prevention and to evaluate its impact on a population.

2. Define a project area. The geographic area defined as the project area for this program announcement must have reported at least 150 cases of P&S syphilis in 1993. An entire State could be defined as the project area for this cooperative agreement, or several counties could be combined to establish the minimum number of syphilis cases. Applications are especially encouraged from rural areas that meet this minimum morbidity requirement (150 cases of P&S syphilis).

3. Undertake the following three research components during Phase I of this cooperative agreement:

A. Analyze the epidemiology of syphilis transmission within the project area with the goal of identifying more efficacious and cost-effective ways to prevent syphilis.

B. Develop an intervention and conduct a pre-implementation of that evaluation. In collaboration with representatives from affected communities, consider hypotheses about barriers to or opportunities for more efficacious and cost-effective innovations in syphilis prevention.

C. Establish surveillance and information systems adequate for monitoring and evaluating innovative syphilis prevention activities.

Note: Traditional disease surveillance for syphilis demonstrates substantial year-to-year variability as well as incompletely understood cyclic oscillations over periods of 5 to 10 years.

During Phase I, you will be expected to implement: (1) A sensitive, population-level surveillance system for syphilis incidence; and (2) a management information system (MIS) for estimating the cost of syphilis prevention, including the costs of collecting and analyzing program data. Although components 1 and 2 are distinct foci of activity that involve different types of expertise, they are related in that interventions that do not focus prevention resources on settings, social contexts, or individuals who help maintain syphilis transmission in the community are unlikely to be effective. Likewise, components 1 and 3 are related in that a sensitive surveillance system that truly reflects incident syphilis cases should have some direct relationship to syphilis transmission events characterized by the ''epidemiologic model'' of syphilis for that community.

4. Include affected communities as partners in the research. Syphilis generally is concentrated in communities with limited resources. In many communities, syphilis is also a stigmatizing condition and one for which the most important consequences (congenital syphilis and facilitation of HIV transmission) often occur unrecognized. Furthermore, some past control efforts and research activities may have damaged community rapport with the health departments and with CDC rather than building trust in a common purpose. Partnerships with communities affected by syphilis, including many African American communities where racism may have a continuing effect, is essential to building trust and to finding solutions.

5. Linkage to other public health programs. Research on syphilis prevention in the 1990s should occur in the context of other major public health program areas. These include:

A. *Prenatal care (required).* The first priority in syphilis prevention is the elimination of congenital syphilis, which can be accomplished through prenatal care for women at risk for syphilis and the appropriate screening for and management of syphilis during pregnancy. However, it is possible that many pregnant women with syphilis have a low risk for transmitting syphilis to other adults, and therefore, are not central to the persistence of syphilis among adults in the community.

B. *HIV Prevention (required).* Communities, sub-populations, and individuals with syphilis are probably at high risk for HIV infection because of common modes of transmission, the usually higher prevalence of syphilis and HIV in the same communities, infection, and the role of genital ulcer diseases as cofactors for sexual transmission of HIV. Syphilis prevention should be coordinated with and should reinforce community intervention strategies and other efforts to change sexual behavior as are associated with HIV prevention. Because syphilis is a curable communicable disease, screening, health care seeking, and treatment will likely play prominent roles in syphilis prevention. Nonetheless, some effort to change behavior must be a component of a responsible syphilis prevention activity, both to prevent HIV infection and other STDs in the community from which one is trying to eliminate syphilis, and to lower the risk of spread if syphilis is reintroduced.

C. *Substance abuse (optional).* A number of studies have shown that crack cocaine was closely linked to local epidemics of syphilis in the late 1980s. People who inject drugs are at high risk for STDs. Effective, innovative, epidemiologically focused syphilis prevention activities may be augmented if they are closely linked to substance abuse treatment. Explain how the proposed syphilis prevention activities interact with, and possibly reinforce, efforts to prevent drug abuse.

D. *Correctional systems (optional).* Because of the association of syphilis with substance abuse and prostitution, collaboration with the criminal justice system (e.g., correctional health programs, probation officers, court referral, juvenile justice) could result in highly effective approaches to syphilis and HIV prevention. Explain any interaction between the proposed syphilis prevention activities and criminal justice programs.

6. Manage, analyze, and interpret data. Data from the three core activities in part 3 should be secure and confidential. In collaboration with CDC, analyze, interpret, and publish data promptly in scientific, programmatic, and policy-making forums. Data should regularly be communicated to community partners in language that they can understand.

7. Build a multidisciplinary research team and program implementation capability. Assemble a multidisciplinary team with the appropriate expertise (such as in microbiology, medicine, epidemiology, behavioral sciences, health care services research) to undertake each of the enumerated steps or activities.

8. Implement a unified core protocol common to all grant recipients that will be established for component 3 of the required activities (population-based surveillance for new syphilis transmissions) and implemented by each recipient. The final core multicenter protocol for component 3 will likely differ somewhat from the protocol specified by any individual recipient. Core protocols or common approaches will be encouraged but will not be required for other components, especially component 1.

9. Each grantee will participate with other recipients and CDC representatives in as many as four meetings during the first 24 months, during which the core protocol for component 3 will be established, and strategies for and progress toward achieving the goals of the program announcement will be assessed.

10. The recipient will share reports on progress toward goals with representatives of communities affected by syphilis and other involved organizations, agencies, and persons.

11. The recipients will take the lead in data analysis and publication of data from their own research centers, with participation and support from CDC.

B. CDC Activities

1. Provide scientific and technical assistance in the general operation of this syphilis prevention project and in the three key research components in Phase I.

2. Within 45 days of the notice of grant award, host a meeting of the successful applicants to develop the core protocol for component 3 and to plan other aspects of the research program. CDC will host as many as three other meetings of investigators during the first 24 months of the project to

promote progress toward core and national objectives.

3. Assist in monitoring and evaluating scientific and operational accomplishments of this syphilis elimination project through periodic site visits for research program reviews, frequent telephone calls, and review of technical reports and interim data analyses.

4. CDC will assist in data analysis and in the presentation and publication of data from Phase I and Phase II activities in scientific, programmatic, and policy-making forums. CDC will actively participate in evaluating the multicenter core protocol data for component 3 (surveillance and evaluation).

Review Conditions and Evaluation Criteria

To be referred to the independent review group for consideration, applications must:

1. Document effective partnerships among research institutions, State or local health departments, and CBOs; and

2. Address the specific requirements in all three research components.

Applications not meeting these two requirements will be returned to the applicant without being reviewed. Applications that meet the preceding requirements will be evaluated according to the following criteria:

1. Understanding of Goals, Purpose, and Context

Understanding of the objectives of this research and evaluation program as reflected in statement of research background, program objectives, and linkage of the specific activities of Phase I to a well-articulated vision of what is needed to substantially reduce the prevalence of syphilis in the United States (5 points). Extent the choice of a project area in which to conduct this research is appropriate to the research objectives and is explained and justified in those terms, and extent in the proposed project area the epidemiology of syphilis, barriers to its reduction or elimination, and resources available to STD/HIV prevention are well-described (5 points). (Total, 10 points.) (APPLICATION CONTENT items 1 and 2.)

2. Quality and Focus of Proposed Phase I Research

The extent to which excellent research designs address the three major components of the program announcement while avoiding extraneous efforts. (APPLICATION CONTENT item 9.)

Component 1: *Innovative uses of epidemiologic methods and findings about syphilis transmission in communities to direct prevention strategies.* The extent to which the proposal is theoretically sound and reflects detailed knowledge of the meaning of the underlying data, such as reported syphilis cases of different durations (primary, secondary, early latent, late latent), reports of sexual contacts among patients, syphilis seroprevalence from screening data, and other data sources. The extent to which the planned approaches to analyzing, interpreting, and using data are innovative and likely to yield new insights into the transmission of syphilis and the opportunities for prevention and elimination within the study community (10 points). The extent to which the findings might be directly translated into public health practice (e.g., changes in screening criteria or the location for syphilis serologic testing; changes in PN practices or priorities; relocation or reorganization of clinical services; development of community-based interventions), and the clarity with which that potential for translation is explained in the application (5 points). (Total, 15 points.)

Component 2: *Development of a programmatic intervention and pilot test of that proposed intervention before large-scale implementation; developing partnerships with communities affected by syphilis.* Choice of an appropriate potential intervention, based on syphilis epidemiology in the study region plus analysis of community, program, or other factors that compose an important barrier or opportunity for more effective, epidemiologic programs (10 points). Scientifically sound plan for evaluating, during this pre-implementation phase, the potential impact of the proposed intervention on syphilis transmission (5 points) and on community perceptions and support for those prevention activities (5 points). The extent to which the planned research findings from this component could be directly translated into public health practice, and the clarity with which that translation is explained in the application (5 points). (Total, 25 points.)

Component 3: *Development of a sensitive syphilis surveillance activity to serve as a basis for evaluating the efficacy and cost-effectiveness of syphilis prevention efforts.* The extent to which the proposal is theoretically sound for evaluating the sensitivity and cost-effectiveness of estimating and following population and sub-population trends in the transmission of syphilis (5 points). The extent to which the proposal demonstrates detailed familiarity with public health disease surveillance and the complexity of trying to change practices in disease surveillance settings proposed (e.g., jails, maternity wards delivery suites) (5 points). Implementation of a management information system adequate for a cost-effectiveness analysis of new approaches to prevention programs 5 points). (Total, 15 points.)

3. Capacity, Interdisciplinary Involvement, and Partnerships

Overall ability of a multidisciplinary research team (including persons in various academic disciplines, public health practitioners, and community collaborators) to perform the technical aspects of the project(s) (i.e., qualified and experienced personnel with a record of excellent scientific achievement) (15 points); appropriate facilities and plans for the administration of the project(s), and a detailed and realistic schedule for the specified activities (5 points). (Total, 20 points: APPLICATION CONTENT items 3, 4, 5, and 6.)

4. Inclusion of Affected Communities

The extent to which communities affected by syphilis are involved in all parts of these research and demonstration activities (5 points). The extent to which the effective work of one or more CBOs is documented in attachments to the application and the collaboration and support of a CBO is thoroughly incorporated into the work of the multidisciplinary team (5 points). (Total, 10 points: APPLICATION CONTENT items 3 and 6.)

5. Linkage to Related Prevention Activities

The extent to which the proposed research agenda and the intervention reflect awareness of other critical prevention services in the community (pre-natal care, HIV, drug abuse, correctional health) and are synergistic or at least well-coordinated with those other preventive health services. (Total, 5 points: APPLICATION CONTENT item 7.)

In addition, consideration will be given to the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds. (APPLICATION CONTENT item 8

Funding Priorities

CDC intends to achieve some geographic diversity of project sites while retaining a principal focus on syphilis in the southeastern United

States. It is the intention to fund at least two Phase I projects that address syphilis in rural areas in the southeastern United States, if those applications are fully competitive.

Interested persons are invited to comment on the proposed funding priority. All comments received on or before May 19, 1995, will be considered before the funding priority is established. If the funding priority should change as a result of any comments received, a revised Announcement will be published in the **Federal Register** and revised applications accepted.

Written comments should be addressed to: Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305, not later than 60 days after due date for receipt of applications. The Program Announcement Number and Program Title should be referenced on the document. CDC does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305. This should be done no later than 60 days after the application deadline date. The granting agency does not guarantee to ''accommodate or explain'' for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or health agency(s) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF 424).

B. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not exceeding one page, and including the following:

1. A description of the population to be served;

2. A summary of the services to be provided; and

3. A description of the coordination plans with the appropriate State and/or local health agencies.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.978, Preventive Health Services—Sexually Transmitted Diseases Research, Demonstration, and Public Information and Education Grants.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Confidentiality

Applicants must have in place systems to ensure the confidentiality of patient records.

HIV/AIDS Requirements

Recipients must comply with the document entitled *Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions* (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS Prevention Program. If the recipient forms its own program review panel, at least one member must also be an employee (or a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

Before funds can be used to develop HIV/AIDS-related materials, determine whether suitable materials are already available at the CDC National AIDS Clearinghouse.

Human Subjects

If your project involves research on human subjects, you must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Provide assurance that the project will be subject to initial and continuing review by an appropriate institutional review committee. You must provide assurance in accordance with the guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Letters of Intent

Letters of intent are required. On or before *May 15, 1995*, submit the original and two copies of a letter of intent to submit an application to: Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305.

Application Submission and Deadline

On or before *July 3, 1995*, submit the original and two copies of the application (Form PHS 5161–1—OMB Number 0937–0189) and one electronic copy on disk to: Henry S. Cassell III, Grants Management Officer, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are:

A. Received on or before the deadline or

B. Sent on or before the deadline date and received in time for submission to the independent review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.A. or 1.B. are considered late applications and will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from: Manuel Lambrinos, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305, telephone (404) 842–6777. Programmatic technical assistance may be obtained from: Sevgi Aral, Ph.D., Division of STD/HIV Prevention, National Center for Prevention Services, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–02, Atlanta, GA 30333, telephone (404) 639–8259.

Please refer to Announcement 523 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 14, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–9879 Filed 4–20–95; 8:45 am]

BILLING CODE 4163–18–P

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for National/Regional Minority Organization Human Immunodeficiency Virus/Sexually Transmitted Diseases Prevention, Immunization, and Tuberculosis Projects—Program Announcement 305b: Amendment of Time and Date

Federal Register Citation of Previous Announcement 60 FR 13728—dated March 14, 1995.

This notice announces an amendment in the time and date of a previously announced meeting.

Previously Announced Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995.

Amendment in Meeting Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995. 8:30 a.m.–4:30 p.m., April 19, 1995.

Dated: April 18, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–10009 Filed 4–19–95; 10:14 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95M–0072]

Cardiac Pacemakers, Inc., Premarket Approval of VENTAK® P2 AICD™ System: Model 1625 VENTAK® P2 Pulse Generator, Model 2835 Software Module, and Model 2815 VENTAK® ECD External Cardioverter Defibrillator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cardiac Pacemakers, Inc., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VENTAK® P2 AICD™ System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 10, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 22, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On August 30, 1993, Cardiac Pacemakers, Inc., St. Paul, MN 55112, submitted to CDRH an application for premarket approval of VENTAK® P2 AICD™ System consists of the following: Model 1625 VENTAK® P2 pulse generator; Model 2835 Software Module to be used with commercially available Cardiac Pacemakers, Inc., (CPI®) Model 2035 Handheld Programmer and Model 6575 or 6577 Telemetry Wand; Model 2815 VENTAK® ECD External Cardioverter Defibrillator (which includes the Model 6873 High Voltage Cable with Model 6838 Thumbscrew, Model 6843 Bipolar Cable with Model 6838 Thumbscrew, Model 6874 Bipolar Cable, and related CPI® commercially available accessories); commercially available CPI® ENDOTAK® 60–Series Lead System and accessories; commercially available CPI® epicardial defibrillation leads and accessories; and commercially available pace/sense leads and accessories. The device is an automatic implantable cardioverter defibrillator system and is indicated for the treatment of patients with ventricular fibrillation and/or ventricular tachyarrhythmias who are at high risk of sudden cardiac death. Such patients are defined as having experienced the following situations: (1) The survival of at least one episode of cardiac arrest presumably due to hemodynamically unstable ventricular tachyarrhythmia not associated with acute myocardial infarction, and/or (2) a poorly tolerated, sustained ventricular tachycardia (VT) and/or ventricular fibrillation (VF) which recurs spontaneously or can be induced despite the best antiarrhythmic drug therapy. Note: The clinical outcome of hemodynamically stable, sustained VT patients is not fully known. A study of the safety and effectiveness of the VENTAK® P2 system on this selected subgroup of VT patients has not been conducted.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this